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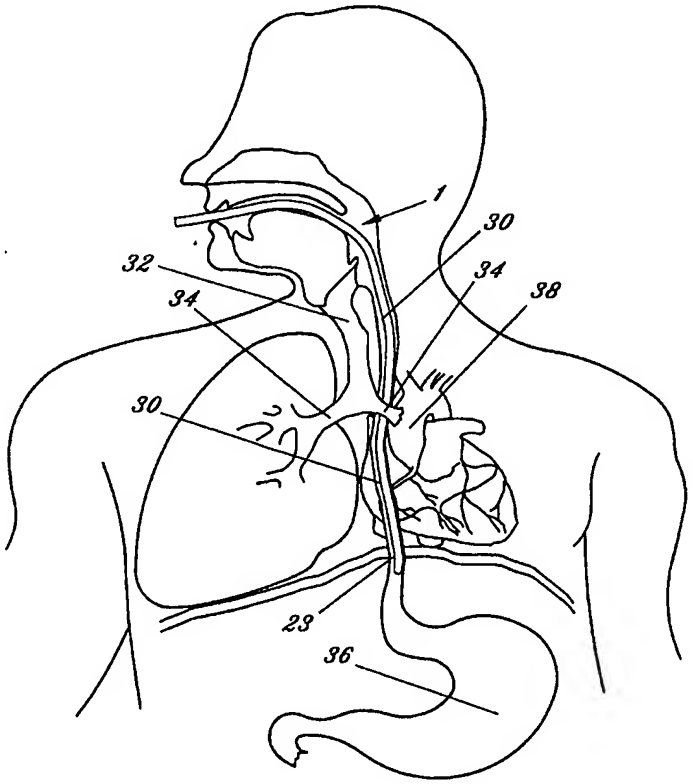
(54) Title: METHOD AND APPARATUS FOR MAINTAINING BODY TEMPERATURE DURING SURGERY

(57) Abstract

A device and method of prevention and treatment of hypothermia for a patient during surgery is provided. An elongated heat exchanger probe is inserted into the patient's esophagus immediately after general anesthesia has been induced, and prior to incision into the patient to maintain core body temperature of the patient, especially in a cool environment such as an operating room. The heat exchanger probe has at least two lumens and is connected at the proximal end to a source of heat exchange media, such as a liquid, kept at a preselected temperature. The distal end of the probe is inserted into the patient's esophagus. The heat exchange media is circulated to the distal end of the probe by a first lumen and returned to the source of media by a second lumen.



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METHOD AND APPARATUS FOR MAINTAINING BODY TEMPERATURE DURING SURGERY

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a method and apparatus for maintaining body temperature during surgery by heat transfer carried out internally of the patient, and more particularly to an apparatus adapted for insertion into the esophagus to provide heat transfer with the aorta and surrounding tissue and a method of use thereof.

2. Description of Related Art

The health benefits of maintaining the body temperature of a patient during surgery to prevent hypothermia is known in the art, and is especially important during more extensive procedures performed on aged and debilitated patients. If hypothermia can be prevented, that is, if the patient's body temperature when departing the operating room can be approximately 37°C, rather than in the range of 34°C to 36° C as is more common, the time spent in the recovery room and in the hospital after surgery, can be reduced, the patient's well being markedly improved, and better outcomes obtained.

Conventional techniques for maintaining body temperature during surgery include the external application of heat directly to the skin of the patient. However, external techniques cannot be applied to the entire surface of the patient during chest and abdominal surgery, and are often ineffective in maintaining a constant body temperature.

Also known are techniques of heat transfer carried out internally of the patient. Typically, catheters and similar devices have been utilized for internal heating or cooling applications.

U.S. Patent No. 5,624,392 to Saab discloses a catheter intended for heat transfer to and from internal regions of the

body. The Saab patent does not disclose the location within the body that the catheter should be inserted, but generally discloses insertion into body cavities, and specifically discloses insertion into blood vessels.

While the Saab patent discloses a general statement about heat transfer, there is no reference to prevention or treatment of hypothermia, nor to placement of a heat transfer device in the region of the aorta.

U.S. Patent No. 5,269,758 to Taheri discloses a method of treatment of hypothermia by insertion of a device into the vascular system through an incision made in the patient's body. However, insertion of a device into the body through an incision is undesirably invasive and complicated to be accepted for general use.

Several other patents disclose invasive insertion of devices. U.S. Patent No. 5,486,208 to Ginsberg discloses a device for controlling a patient's temperature that is inserted into a blood vessel. U.S. Patent No. 5,211,631 discloses a device used to mix warm fluids with the patient's blood, and is administered through an incision in the body. U.S. Patent No. 4,111,209 to Wolvek et al. discloses an invasive device used to cool the heart during surgery. And, U.S. Patent No. 5,281,213 to Milder et al. discloses an ablation device to apply cold to specific regions of the heart to destroy certain parts of the heart's conduction mechanism.

U.S. Patent No. 5,571,153 to Wallsten discloses a device and method for hyperthermia treatment of certain cancers. The device applies heat in excess of 42° C. in a limited and focused area of the body, and is disclosed as inserted into a body cavity or canal. U.S. Patent No. 5,549,559 to Eshel discloses a device for a similar application of thermal treatment of tissues.

None of the devices or methods heretofore disclosed are easy to use and effective to maintain body temperature during surgery.

SUMMARY OF THE INVENTION

The present invention is to an apparatus and method for prevention and treatment of hypothermia for a patient during surgery. According to the present invention, an elongated heat exchanger probe is inserted into the patient's esophagus immediately after general anesthesia has been introduced, and prior to commencement of the surgical procedure. The purpose of the heat exchanger is to maintain a predetermined core body temperature of the patient, especially in a cool environment such as an operating room.

The heat exchanger probe, fully described hereinbelow, is connected at the proximal end to a source of heat exchange media kept at a preselected temperature. The heat exchange media used is preferably a liquid, and is preferably either water, saline, or other media that would be harmless if introduced directly into the esophagus. The heat exchange media is circulated to the distal end of the probe by a first lumen, and is returned to the source of heat exchange media by a second lumen which is preferably coaxially arranged within the first lumen.

The timing of placement of the device, immediately after general anesthesia has been introduced and prior to incision into the patient, is important in order to combat hypothermia before it actually begins, and to maintain a steady body temperature during the entire operation.

The placement of the device within the esophagus is also important. The esophagus is adjacent the aorta, which has a very high flow rate of cardiac output, typically 3 to 6 liters per minute for most patients. The esophagus is also adjacent the posterior aspect of the heart, creating an ideal heat exchange location with extremely high blood flow rates in close proximity to the heat exchanger probe. Therefore, very rapid and efficient exchange of calories is provided, even with very small temperature gradients.

Placement into the esophagus eliminates the necessity of making an incision into the patient to insert the probe. Furthermore, plastic tubes are routinely inserted into the

esophagus in operating rooms around the world, and are considered safe, simple, and easy to use. For example, esophageal stethoscopes are in common use.

The heat exchanger probe can be a pliable, flexible tube that includes at least two lumens used to circulate the heat exchange media from the proximal end to the distal end of the probe. The proximal end of the probe is connectable to a source of heat exchange media that is maintained at a preselected temperature. The distal end of the probe is inserted into the esophagus.

In one embodiment, a first lumen supplies heat exchange media from the source of heat exchange media at the proximal end toward the distal end of the probe where heat is transferred directly into the patient at the aorta. A second lumen returns the heat exchange media from the distal end to the proximal end to be returned to the media source. In this manner, media at a constant temperature flows through the heat exchanger probe adjacent the aorta where efficient heat exchange with the patient takes place.

The probe is preferably an elongated disposable catheter made of plastic or equivalent material known in the art, and can be approximately 12-15 mm in diameter and 20-25 cm long. The proximal end can include a quick disconnect fitting for attachment to the source of heat exchange media.

The probe can include a temperature probe at the distal end to determine the temperature within the esophagus of the patient.

Accordingly, it is an objective of the present invention to provide a method to prevent and treat hypothermia during surgery by use of an esophageal heat exchanger.

It is a further objective of the present invention to provide a catheter for insertion into the esophagus having at least two lumens to circulate heat exchange media at a preselected temperature to exchange heat with a patient.

In accordance with these and other objects which will become apparent hereinafter, the instant invention will now be

described with particular reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is schematic view of the present invention.

Figure 2 is a schematic view of the heat exchanger probe of the present invention.

Figure 3 is a cross-sectional view taken along line 3-3 of Fig. 2.

Figure 4 and 5 are schematic views of the heat exchanger probe inserted into an esophagus.

Figure 6 is schematic view of a portion of the human anatomy illustrating the esophagus and aorta.

Figure 7 is a cross-sectional view taken along line 6-6 of Fig. 5.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Fig. 1, the preferred embodiment of the present invention is illustrated including heat exchanger probe 1, heat exchange media storage tank 2, and heat exchanger 4. Heat exchange media storage tank 2 can contain a supply of heat exchange media 3, which is preferably a liquid and preferably water, saline, or other media that would be harmless if placed directly into the esophagus. Heat exchange media 3 exits tank 2 and enters heat exchanger 4 at exit fitting 8.

For treating hypothermia, heat exchange media 3 must be heated and maintained at a preselected temperature. To accomplish this, a heat exchanger 4 can be utilized to heat media 3. Heat exchanger 4 can be any suitable type of heat exchange device such as illustrated including heating element 10 with thermostat 12. Thermostat 12 can include a fail-safe shutoff set to a predetermined temperature to prevent over-heating of heat exchange media 3. Coil 5 can wrap around element 10 for efficient heat transfer. Coil 5 can be made of metal such as stainless steel, or other equivalent metal that transfers heat well, and is corrosion resistant.

Heat exchange media 3 must be maintained as close as possible to the desired temperature for heating or cooling the patient. For hypothermia treatment as described herein, or to maintain the patient's body temperature at a constant 37° celsius (C) for an entire procedure, heat exchange media 3 should be maintained in the range of approximately 37° to 41° C, and is preferably kept at a constant temperature of approximately 39° C. For cooling the patient, heat exchanger 4 would be replaced with a cooling element (not shown).

Heat exchange media 3 exits heat exchanger 4 at exit fitting 14, and enters quick disconnect fitting 17 through input conduit 19. Pump 18, which can be a suitable conventional pump, may be utilized to circulate media 3, as described herein. The preferred direction of media 3 flow is illustrated by the direction of the arrows in Figs. 1 and 2.

Referring to Figs. 2 and 3, heat exchanger probe 1 can include at least two lumens 20 and 22. Lumens 20 and 22 are preferably concentric, with lumen 22 disposed within lumen 20. Lumen 20 is connected to quick disconnect fitting 16 at proximal end 21 of probe 1, as shown in Fig. 1. When quick disconnect fitting 16 is mated with quick disconnect fitting 17, lumen 20 is in fluid communication with input conduit 19.

Lumen 20 is the input lumen to probe 1. Heat exchange media 3 flows into input conduit 19, through fittings 17 and 16, and into lumen 20, and on to the distal end 23 of probe 1, as shown in Fig. 1. Media 3 can then flow through a plurality of return apertures 24 into lumen 22.

Lumen 22 is the output lumen to probe 1. Lumen 22 is connected at proximal end 21 of probe 1 to quick disconnect fitting 16. When quick disconnect fitting 16 is mated with quick disconnect fitting 17, lumen 22 is in fluid communication with output conduit 26. Output conduit 26 is connected to tank 2 at input fitting 28. Media 3 returning from apertures 24 at distal end 23 of probe 1, flows through lumen 22, through fittings 16 and 17, through conduit 26, and back to tank 2.

Probe 1 can be made of plastic or equivalent material known in the art, and is preferably disposable from distal end 23 to quick disconnect fitting 16. Probe 1 preferably has at least two lumens, one for heat exchange media input and one for heat exchange media output, but could have any number of additional lumens. Probe 1 can be an elongated tubular member with any cross-sectional shape, with circular being the preferred embodiment.

To measure the temperature of the heat exchange media 3, a temperature probe 6 can be placed within probe 1 at distal end 23, as shown in Fig. 1. Placing temperature probe 6 at distal end 23 of probe 1 ensures that media 3 is kept at the correct temperature while within the patient. Temperature probe 6 can include wire 7 which preferably connects directly to thermostat 12. Alternately, wire 7 can connect to a temperature probe indicator, as known in the art (not shown).

Referring to Fig. 4, insertion of distal end 23 of probe 1 into esophagus 30 is illustrated along with the relationship to trachea 32, bronchi 34, stomach 36, and diaphragm 37. Fig. 4 also shows the relationship between the esophagus 30 and the aorta 38. Blood flows through the aorta at a rate of approximately 3 to 6 liters per minute in most patients. Because the esophagus is adjacent the aorta 38, heat is readily transferred from heat exchange media 3 in lumen 20, through esophagus 30 to aorta 38, to be circulated by blood flow in the patient.

Probe 1 is inserted into esophagus 30 after general anesthesia is induced and prior to making an incision into the patient. The length of distal end 23 of probe 1 must be long enough to be positioned as illustrated in Fig. 4, and still allow the proximal end 21 to be connected to quick disconnect fitting 16 which is connectable to fitting 17, as shown in Fig. 1. Preferably, distal end 23 of probe 1 is approximately 12-15 mm in diameter and 20-25 cm long.

Fig. 5 illustrates why it is desirable that lumen 20 be the input lumen. Heat exchange media 3 flowing into lumen 20 places

the heated media 3 adjacent esophagus 30 for more efficient heat exchange. Return lumen 22 then returns media 3 after heat has been transferred to the patient from lumen 20.

The instant invention has been shown and described herein in what is considered to be the most practical and preferred embodiment. It is recognized, however, that departures may be made therefrom within the scope of the invention and that obvious modifications will occur to a person skilled in the art.

CLAIMS

What Is Claimed Is:

1. A heat transfer apparatus for insertion into an esophagus, comprising:

an elongated tubular member having a first and a second lumen being defined by substantially coaxial outer and inner walls, respectively, of said tubular member, said first and said second lumens disposed substantially coaxial relative to each other and each extending from a proximal end to a distal end of said tubular member, said distal end insertable into the esophagus;

a plurality of apertures disposed in said inner wall of said tubular member at said distal end to place said first lumen and said second lumens in fluid communication with each other;

a source of liquid at a preselected temperature, said source of liquid removably connectable to said tubular member at said proximal end, said source of liquid having a liquid outlet connectable in fluid communication to said first lumen and a liquid inlet connectable in fluid communication to said second lumen; and

means for circulation of a liquid from said source of liquid at a preselected temperature through said first lumen to said distal end of said tubular member and through said second lumen back to said source of liquid.

2. The apparatus of claim 1, wherein said source of liquid at a preselected temperature includes means for heating and maintaining the temperature of liquid at the preselected temperature.

3. The apparatus of claim 2, wherein said preselected temperature is approximately 37° to 41° celsius.

4. The apparatus of claim 3, wherein said preselected temperature is approximately 39° celsius.

5. The apparatus of claim 1, further including means for quick disconnection between said source of liquid and said proximal end of said tubular member, said tubular member being disposable between said distal end and said means for quick disconnection.

6. A method for prevention and treatment of hypothermia during surgery, comprising the steps of:

a) providing:

an elongated tubular member having a first and a second lumen being defined by substantially coaxial outer and inner walls, respectively, of said tubular member, said first and said second lumens disposed substantially coaxial relative to each other and each extending from a proximal end to a distal end of said tubular member, said distal end insertable into the esophagus, a plurality of apertures disposed in said inner wall of said tubular member at said distal end to place said first lumen and said second lumens in fluid communication with each other;

a source of liquid at a preselected temperature in the range of approximately 37° to 41° celsius, said source of liquid removably connectable to said tubular member at said proximal end, said source of liquid having a liquid outlet connectable in fluid communication to said first lumen and a liquid inlet connectable in fluid communication to said second lumen; and

means for circulation of a liquid from said source of liquid at a preselected temperature through said first lumen to said distal end of said tubular member and through said second lumen back to said source of liquid;

b) inducing general anesthesia in a patient;

c) inserting said distal end of said elongated tubular member into an esophagus of the patient so that at least a portion of said tubular member is adjacent the aorta; and

d) transferring heat from said liquid flowing in said tubular member to blood flowing in the patient.

7. The method of claim 6 further including the step of:

e) performing a surgical procedure on the patient.

8. The method of claim 6 wherein said preselected temperature is approximately 39° celsius.

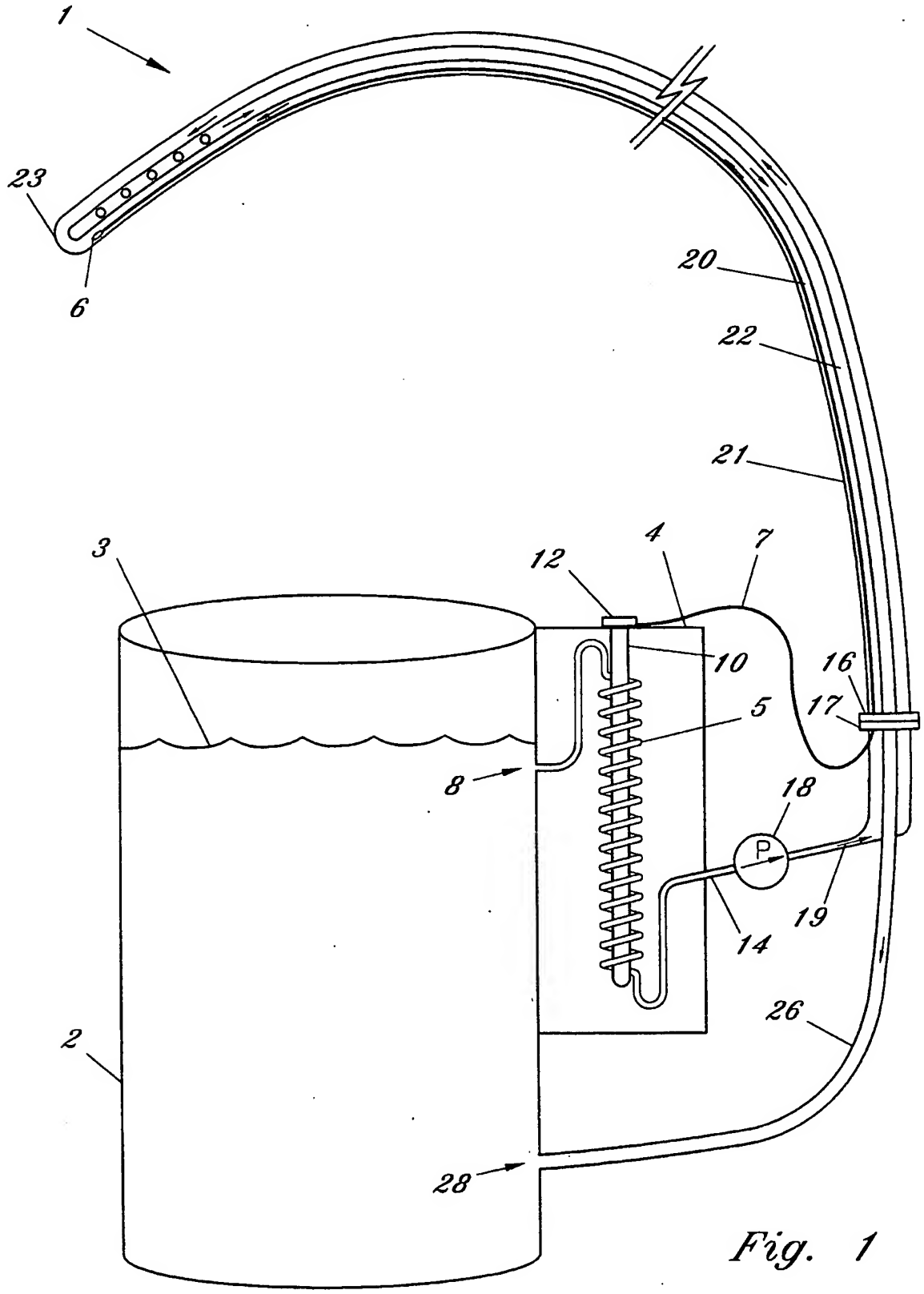

Fig. 1

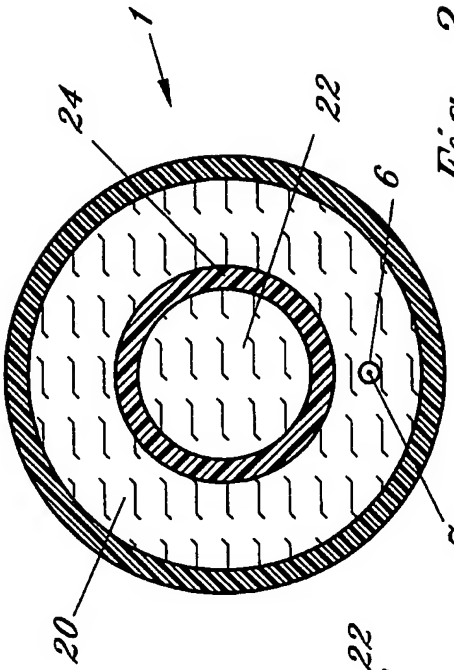

Fig. 3

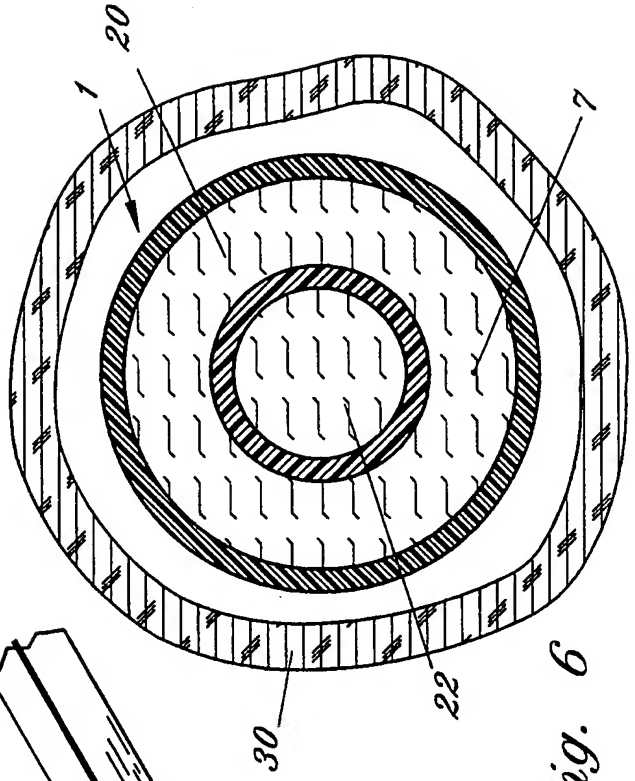

Fig. 6

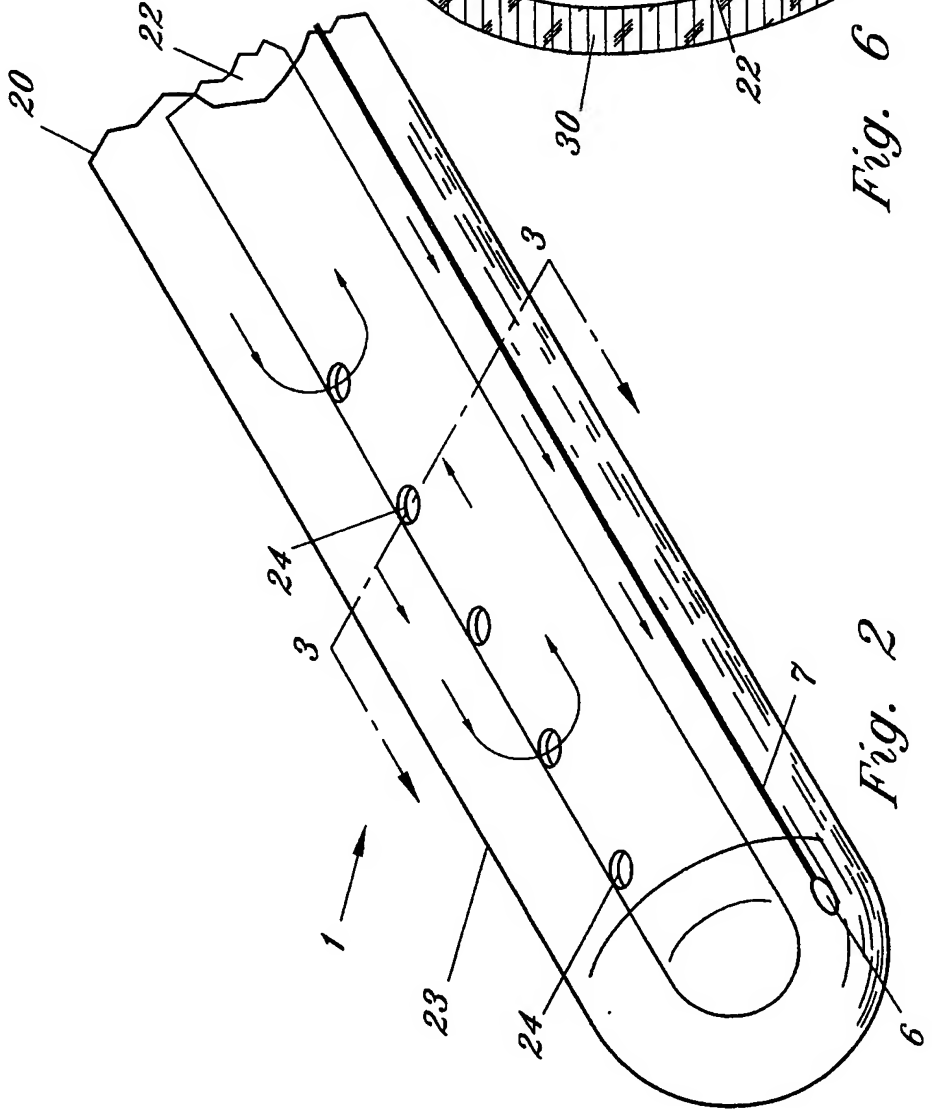

Fig. 2

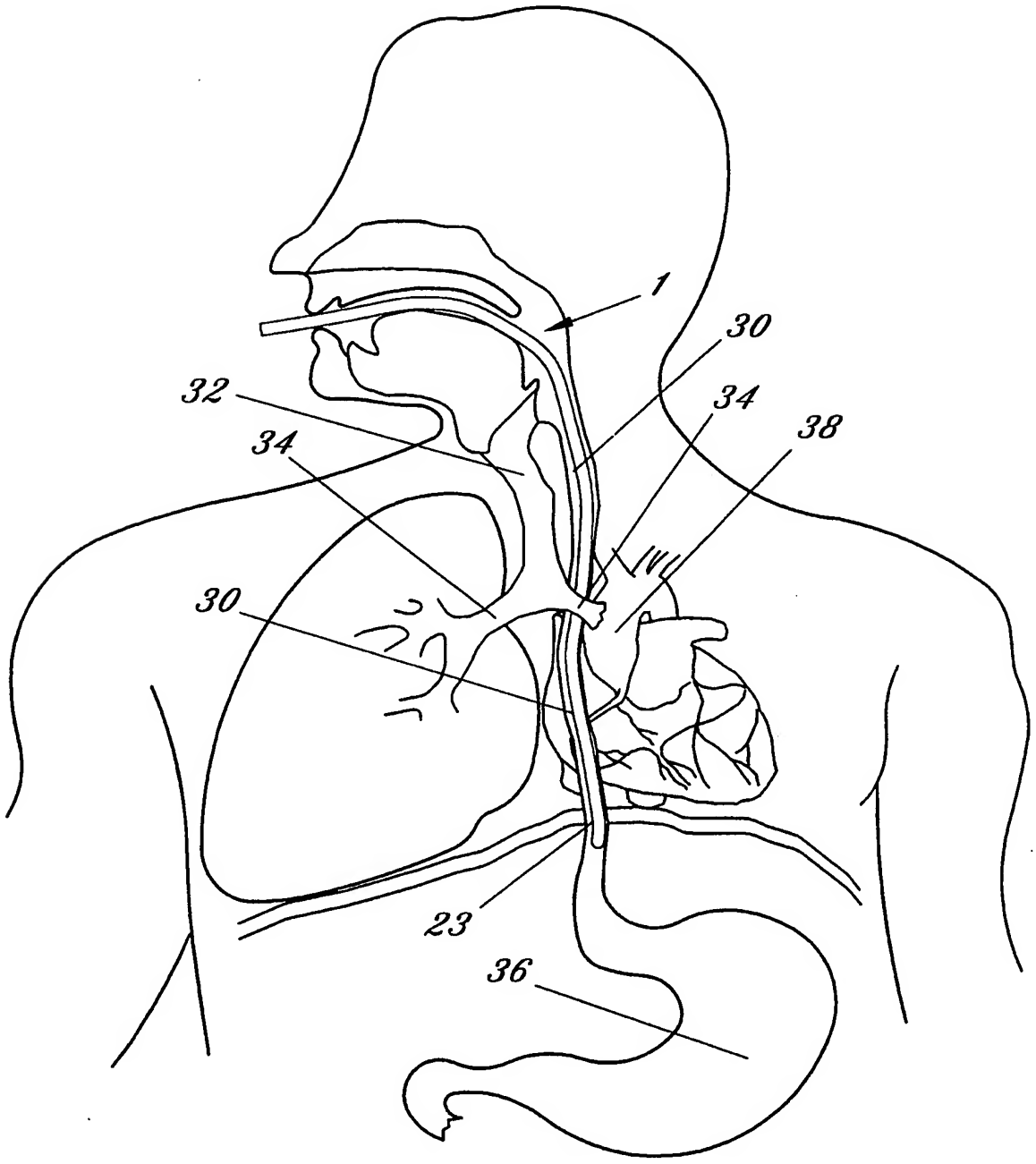

Fig. 4

INTERNATIONAL SEARCH REPORT

Intern .al Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F7/12 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61M

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 269 758 A (TAHERI) 14 December 1993 cited in the application see the whole document	1-5
Y	US 5 531 776 A (WARD ET AL.) 2 July 1996 see column 9, line 16 - line 64 see claim 1; figure 16	1-5
A	US 5 624 392 A (SAAB) 29 April 1997 cited in the application see figures 1,9	1
A	WO 94 17842 A (CRYOMEDICAL SCIENCES) 18 August 1994 see abstract; figures 2-6	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Information on patent family members

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